



Data Sharing Policy

1 INTRODUCTION

The George Institute for Global Health (the **Institute**) strongly supports the view that:

- publicly funded research data are a public good which should be made available with as few restrictions as possible;
- greater data sharing could enhance public well-being by maximising utilisation of gained knowledge, reducing redundant research and facilitating scientific innovation; and
- the approach to scientific data sharing must be responsible and must recognise legal, regulatory, ethical and commercial constraints.

For this reason, the Institute formulated a policy and processes to allow appropriate and responsible sharing of the Institute's research data for scientific research.

2 SCOPE

This Data Sharing Policy (Policy) covers all studies conducted by the Institute globally and regardless of the source of funding. This policy applies to data sharing requests concerning prospective and completed Institute studies. In developing this Policy, the Institute was guided by the following principles for responsible sharing of clinical trial data formulated by the Institute of Medicine, while recognising that these principles extend to a broader range of study designs:

- maximise the benefits of clinical trials while minimising the risks of data sharing;
- respect individual participants whose data are shared;
- increase public trust in clinical trials and the sharing of trial data;
- conduct the sharing of trial data in a fair manner; and
- appropriately manage conflicts of interest.

3 DEFINITION

Data Sharing Agreement	an agreement between the Institute and a Requester which sets out the terms upon which the Institute agrees to provide the Requester with access to certain data in a Collection for the purposes set out in the relevant approved Proposal.
Collection	a research dataset, including summary datasets, or set of human samples with associated data, in respect of a study conducted by the Institute.

Custodian	the individual, organisation, body or committee with responsibility for the relevant Collection. Typically, this is the principal investigator (PI) or chair of the study Steering Committee. For on-going studies with an active PI, the PI will be considered the Custodian.
Data Sharing Committee	the Committee that is responsible for updating the Policy, providing Institute staff with guidance on the Policy and related procedures. The Committee monitors and oversees data access and sharing requests in respect of data in a Collection and decides on requests where the study in question no longer has an active Custodian. Membership of the Committee is determined by the Research and Impact Committee (RIC). However, it must include Director, Centre for Operational and Research Excellence (CORE) and senior representatives from the Institute's Biostatistics and Data Science Division. The Data Sharing Committee meets monthly and reports to the RIC.
Data Sharing Coordinator	an individual responsible coordinating the Data Sharing Committee. The role is held by the Institute's Head, Data Management.
Research and Impact Committee	the Institute's committee principally responsible for Institute's research strategy and its implementation.
Proposal	means a proposal submitted by a Requester in accordance with section 4 of this Policy.
Requester	an individual or a group of researchers seeking access to data from a Collection.

4 RESPONSIBILITIES OF THE INSTITUTE'S INVESTIGATORS

The Institute's Investigators will:

- design research studies and manage research data with the expectation that data will be shared;
- have in place a Data Management Plan (DMP) and sharing plan, for all projects sponsored by the Institute with a clear scope for wider research use and sharing potentials.
- share data from research activities in accordance with this Policy and the terms and conditions of applicable grants and contracts; and
- abide by the International Committee of Medical Journal Editors' (ICMJE) requirements that:
 - as of 1 July 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement (Appendix A refers);
 - clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. If the data sharing plan changes after

registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

In addition, the Institute's Investigators must take into consideration local / regional requirements and regulations regarding data sharing.

4.1 DATA SHARING: Eligibility, Terms of Sharing, Period of Unavailability, and Limits on Data Sharing

4.1.1 Eligibility

- The data sharing will be only for the purposes of health and medical research and within the constraints of the consent under which the data were originally gathered.
- The Custodian of the Collection will not consider any Proposals for data sharing that unblind, or potentially unblind, randomised comparisons in active / ongoing trials.
- Requesters should be employees of a recognised academic institution, health service organisation, commercial research organisation or from the pharmaceutical industry. Requesters must have experience in medical research.
- Requesters must be able to demonstrate through their peer review publications in the area of interest their ability to carry out the proposed use of the requested dataset from a Collection.
- The Requesters must not have a conflict of interest that may potentially influence their interpretation of any analyses. Requesters must declare all actual or potential conflicts of interest in relation to the requested dataset or to previous research conducted by the Requesters. Requesters must also declare funding sources for the requested work for which the requested dataset will be used, and update the Institute about subsequent funding sources that are secured after the data are shared with them. All such conflicts of interest and funding sources must also be declared in all publications and presentations resulting from the shared dataset. The Institute reserves the right to refuse sharing its data in the face of potential adversarial conflicts of interest.

4.1.2 Terms of Sharing

- Requester will be required to enter into a Data Sharing Agreement with the Institute, which meets the Institute's data sharing requirements.
- Data supplied from a Collection may be transferred only to Requester(s) named in the original application and as specified in the relevant Data Sharing Agreement. Data from the Collection may not be transferred to individuals outside the Requester's research group.
- Supplied data must only be used for the purpose described in the Proposal as further stipulated in the Data Sharing Agreement.

- All data provided to a Requester will be de-identified and identifying data will not be made available to Requesters. The processes for de-identification will be as stated by the relevant study Custodian or the Data Sharing Committee.
- The Requester and individuals within his/her research group must not attempt to identify any individual from the data provided. Should the Requester or individuals within his/her research group believe that they inadvertently identified any individual, they must not record such identifiable data, or share the identification with any other person or attempt to contact the individual. Such identification must be promptly reported to the Institute.
- Recipients must agree not to link the de-identified data provided with any other dataset without the permission from the Custodian or Data Sharing Committee.

4.1.3 Period of Data Unavailability

It is the Institute's policy that the full data package (comprising the full analysable data set, the full protocol, the full statistical analysis plan, and the analytic code) may be shared with eligible Requesters after a reasonable period following study publication, as defined by the Custodian or Data Sharing Committee. The decision on whether or not to share such data will remain with the Custodian or Data Sharing Committee, taking into account any legal, regulatory and ethical considerations.

4.1.4 Limits on Data Sharing

For some research, delays or limits on data sharing may be necessary and appropriate to:

- safeguard research participants. In particular, for research involving samples or information pertaining to human subjects, data must be managed and shared in a way that is fully consistent with the terms of the consent under which samples and data were provided by the research participants;
- allow appropriate opportunity to exploit the dataset for additional pre-specified hypotheses, gain intellectual property protection or to the further development of a technology for public benefit;
- protect against clear conflicts of interest, where analyses may be requested to support commercial aims rather than those related to the broader public good; or
- meet other legal (including contractual), regulatory, or ethical obligations.

The Data Sharing Committee will carefully consider the potential implications of sharing data with a third party, if the third party may derive commercial benefits from the data sharing. Delays or limits on data sharing may be necessary in such circumstances. The Data Sharing Committee retains absolute discretion to decide whether access is provided to commercial entities or parties associated or perceived to be associated with such entities.

NB. For prospective studies, consent procedures should include provision for data sharing in a way that maximises the value of the data for wider research use, while providing adequate safeguards for participants. As part of the consent process,

proposed procedures for data sharing should be clearly set out. Current and potential future risks associated with this should be explained to research participants. In designing studies, researchers must ensure that they have appropriate systems to protect the confidentiality and security of data pertaining to human subjects, and minimise any risks of identification by data users. This can be achieved through the use of appropriate anonymisation procedures and managed data sharing processes. Such systems should be sufficient to safeguard participants, but proportionate to the level of sensitivity of the data and associated risk. They should not unduly inhibit responsible data sharing for legitimate research uses.

4.2 DATA MANAGEMENT AND SHARING: PROCESSES

It is the Institute's requirement that Investigators have in place a DMP and sharing plan. This requirement applies to all projects sponsored by the Institute including generating significant datasets that could be shared for added value – for example, those where the data has clear utility for research questions beyond those that the data generators are seeking to address.

The TGI Data Management Plan SOP and template are available in G-Wiz:
<https://sp.georgeinstitute.org/CORE/PoliciesAndSOPs/SOPs/Forms/DM.aspx>.

The DMP must be updated when the data management systems or processes of the research project change significantly from those captured in the current DMP.

4.2.1 Data Sharing: Processes

- In the first instance, potential Requesters are strongly encouraged to approach the relevant study investigators informally to discuss feasibility of data sharing. Study investigators can refer such requests to the Data Sharing Coordinator (Head, Data Management).
- A formal outline of the proposed study is to be submitted to the Data Sharing Coordinator for consideration. The Proposal (max 3 pages) must include a clear statement of the background to the proposed data use, the objectives and details of the methodology proposed, and relevant references. In the outline, Requesters must demonstrate through their peer review publications in the area of interest their ability to carry out the proposed study.
- Proposals will then be forwarded as appropriate to the Custodian or to the Data Sharing Committee who will designate an appropriate senior scientist at the Institute to act as the Institute's Custodian (i.e. an Acting Custodian) for the Proposal. The Custodian or the Acting Custodian will liaise with the Requester to ensure that Proposal is scientifically sound and achievable by the proposed data sharing.
- The Custodian or the Acting Custodian will decide whether or not to approve the Proposal and allow access to the relevant data within the Collection. Any approval by Custodian or the Acting Custodian is subject to review by the Data Sharing Committee as part of their monitoring of data sharing requests.

- Proposals that are not approved will also be reviewed by the Data Sharing Committee and Requesters may appeal to the Data Sharing Committee if they disagree with the Custodian's or Acting Custodian's refusal.
- Ethics Committee approval from the Requester's ethics committee is the Requester's responsibility. The Requester may also need to obtain approval from the Research Ethics Committee responsible for the existing Institute study.
- Where demand exceeds availability of staffing resources to make the data available, access will be prioritised by the data Custodian and the Data Sharing Committee on scientific merit.
- Requesters will be required to cover the costs of administering the data sharing (including legal fees if applicable), retrieving, processing and sending the data. The estimated costs for a particular request will be provided after initial review of the application.
- Access to data in the Collection will only be permitted by application and only under an active Data Sharing Agreement.

4.3 DISSEMINATION OF RESEARCH RESULTS AND TRANSPARENCY

The Institute reserves the right to publish the title, the names(s) and affiliations(s) of the PI(s), a lay summary and a scientific abstract of each piece of collaborative research for which access to the data in a Collection has been granted, before identification or publication of results. Requesters who do not wish details of their study to be openly available should state this in their Proposal and give reasons.

The Institute staff will usually have significant insight into shared data and would usually be able to add value to publications utilising the data in a Collection. It would be expected that an Institute representative of the original study would be involved as a collaborator on studies resulting from the shared data and be offered co-authorship on resulting publications or presentations. It may be appropriate to acknowledge members of the original study staff who have contributed directly to the original study in order that they may claim authorship as members of the study team.

Each paper to be submitted for publication by collaborators must be forwarded to the appropriate Custodian or Acting Custodian for consideration at least 28 days before submission.

The Institute's policy and processes on data sharing will be reviewed periodically, and at least every twelve months to keep abreast of the rapidly developing ideas around data sharing globally.

4.4 REFERENCES

- NHMRC Statement on Data Sharing
- Wellcome Trust: Policy on Data Management and Sharing

- Darren B Taichman, Joyce Backus, Christopher Baethge, Howard Bauchner, Peter W de Leeuw, Jeffrey M Drazen, John Fletcher, Frank A Frizelle, Trish Groves, Abraham Haileamlak, Astrid James, Christine Laine, Larry Peiperl, Anja Pinborg, Peush Sahni, Sinan Wu. Sharing Clinical Trial Data: A Proposal from the International Committee of Medical Journal Editors. *The Lancet*. Volume 387, No. 10016, e9–e11, 23 January 2016.

5 REVISION HISTORY

Version number	Replaces	Reason/description of change
V4.0 (Jan 2024)	V3.0	Minor edits including: <ul style="list-style-type: none"> • change of the Data Sharing Coordinating Committee's name to that of Data Sharing Committee • timing of Data Sharing Committee meetings • change of 'Statistic and Data Management' (division) to 'Biostatistics and Data Science' (division) • Updates to the roles of the Data Sharing Committee and Data Sharing Coordinator • Align DMP and sharing plan requirements with the Research DM policy
V3.0 (Sept 2021)	V2.0	Minor edits to Data Sharing committee and new template
V2.0 (Aug 2018)	V1.0	Nil to compare
V1.0 (unknown)	NA	New

6 APPROVAL

Title of Owner / Author	
Approved by: COO / Director	

APPENDIX A

DATA SHARING STATEMENT: ICJME REQUIREMENTS

The Institute adopts ICMJE requirements regarding data sharing statements. In particular, we adopt the view that data sharing statements must indicate the following:

- whether individual de-identified participant data (including data dictionaries) will be shared;
- what data in particular will be shared;
- whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, data dictionary, etc.);
- when the data will become available and for how long;
- by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).'

Examples of data sharing statements that fulfil ICMJE requirements*

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices)	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures and appendices)	Not available
What other documents will be available?	Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code	Study protocol, statistical analysis plan, analytic code	Study protocol	Not available
When will data be available	Immediately after publication. No end date	Beginning 3 months and ending 5 years after article publication	Beginning 9 months and ending 36 months after article publication	Not applicable

	Example 1	Example 2	Example 3	Example 4
(start and end dates)?				
With whom?	Anyone who wishes to access the data	Researchers who provide a methodologically sound proposal	Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose	Not applicable
For what types of analyses?	Any purpose	To achieve aims in the approved proposal	For individual participant data meta-analysis	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at (<i>Link to be included</i>).	Proposals should be directed to xxx@yyy. To gain access, data requesters will need to sign a data access agreement. Data are available for 5 years at a third party website. (<i>Link to be included</i>)	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our university’s data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (<i>Link to be provided</i>).	Not applicable

*These examples are meant to illustrate a range of, but not all, data sharing options.